

WE CLAIM:

1. A DNA vaccine effective for eliciting an immune response against cells that present a carcinoembryonic antigen (CEA) comprising:

- (a) a plasmid DNA operably encoding a CEA; and
(b) a plasmid DNA operably encoding a CD40 ligand;

together with a pharmaceutically acceptable carrier.

2. The DNA vaccine of claim 1 wherein the DNA operably encoding a CEA and the DNA operably encoding a CD40 ligand are both incorporated in the same plasmid.

3. The DNA vaccine of claim 1 wherein the DNA operably encoding a CEA and the DNA operably encoding a CD40 ligand are each incorporated in separate plasmids.

4. The DNA vaccine of claim 1 wherein both plasmid DNAs are operably incorporated in an attenuated bacterial delivery vector.

5. The DNA vaccine of claim 4 wherein the bacterial delivery vector is a bacterium selected from the group consisting of attenuated *Salmonella typhimurium* and attenuated *Listeria monocytogenes*.

6. The DNA vaccine of claim 1 wherein both plasmid DNAs are operably incorporated in an attenuated viral vector.

7. The DNA vaccine of claim 6 wherein the viral vector is an attenuated form of a virus selected from the group consisting of a Herpes virus, an Adenovirus, a Vaccinia virus, and an Avipox virus.

8. The DNA vaccine of claim 1 wherein both plasmid DNAs are operably incorporated in an attenuated *Salmonella typhimurium* delivery vector.

9. The DNA vaccine of claim 1 wherein the CD40 ligand is CD40LT.

10. A method of immunizing a mammal against cancer cells that present a carcinoembryonic antigen (CEA) which comprises the step of administering to the mammal an effective immune response eliciting amount of a DNA vaccine comprising a plasmid DNA operably encoding a CEA, and a

plasmid DNA operably encoding a CD40 ligand, in an amount sufficient to elicit an immune response against cells that present a CEA.

11. The method of claim 10 wherein the mammal is a human.

12. The method of claim 10 wherein both plasmid DNAs are operably incorporated in an attenuated bacterial delivery vector.

13. The method of claim 12 wherein the bacterial delivery vector is a bacterium selected from the group consisting of attenuated *Salmonella typhimurium* and attenuated *Listeria monocytogenes*.

14. The method of claim 10 wherein both plasmid DNAs are operably incorporated in an attenuated viral delivery vector.

15. The method of claim 14 wherein the viral delivery vector is an attenuated form of a virus selected from the group consisting of a Herpes virus, an Adenovirus, a Vaccinia virus, and an Avipox virus.

16. The method of claim 10 wherein the CD40 ligand is CD40LT.

17. The method of claim 10 wherein the cells presenting a carcinoembryonic antigen are colon cancer cells.

18. The method of claim 10 wherein the vaccine is administered orally.

19. The method of claim 10 wherein the DNA operably encoding a CEA and the DNA operably encoding a CD40 ligand are both incorporated in the same plasmid.

20. The method of claim 10 wherein the DNA operably encoding a CEA and the DNA operably encoding a CD40 ligand are each incorporated in separate plasmids.

21. A method of immunizing a mammal against cancer cells that present a carcinoembryonic antigen (CEA) comprising the steps of:

(a) administering to the mammal an immune response eliciting amount of a DNA vaccine comprising a plasmid DNA operably encoding a CEA, and a plasmid DNA operably encoding a CD40 ligand; and

(b) administering to the mammal an immune response enhancing amount of recombinant antibody fusion protein huKS1/4-IL2 in a pharmaceutically acceptable carrier.

22. The method of claim 21 wherein the mammal is a human.

5 23. The method of claim 21 wherein both plasmid DNAs are operably incorporated in an attenuated bacterial delivery vector.

24. The method of claim 23 wherein the bacterial delivery vector is a bacterium selected from the group consisting of attenuated *Salmonella typhimurium* and attenuated *Listeria monocytogenes*.

10 25. The method of claim 21 wherein both plasmid DNAs are operably incorporated in an attenuated viral delivery vector.

26. The method of claim 25 wherein the viral delivery vector is an attenuated form of a virus selected from the group consisting of a Herpes virus, an Adenovirus, a Vaccinia virus, and an Avipox virus.

15 27. The method of claim 21 wherein the CD40 ligand is CD40LT.

28. The method of claim 21 wherein the cells presenting carcinoembryonic antigen are colon cancer cells.

20 29. The method of claim 21 wherein the vaccine is administered orally.

30. The method of claim 21 wherein the recombinant antibody fusion protein huKS1/4-IL2 is administered intravenously.

25 31. The method of claim 21 wherein the DNA operably encoding a CEA and the DNA operably encoding a CD40 ligand are both incorporated in the same plasmid.

32. The method of claim 21 wherein the DNA operably encoding a CEA and the DNA operably encoding a CD40 ligand are each incorporated in separate plasmids.

30 33. A kit comprising a vaccine of claim 1 packaged in a hermetically sealed, sterile container, the container having a label affixed thereto, the label bearing printed material identifying the vaccine, and providing information useful to an individual administering said vaccine to a patient.

34. The kit of claim 33 wherein the CD40 ligand is CD40LT, and both plasmid DNAs are operably incorporated in an attenuated *Salmonella typhimurium* delivery vector.

35. The kit of claim 33 further comprising a recombinant antibody fusion protein huKS1/4-IL2, together with a pharmaceutically acceptable carrier, packaged in a hermetically sealed, sterile container, the container having a label affixed thereto, the label bearing printed material identifying the fusion protein and providing information useful to an individual administering said fusion protein to a patient.

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